

K053003

NOV 22 2005

**SUMMARY OF SAFETY AND EFFECTIVENESS**

**NAME OF FIRM:** DePuy Orthopaedics, Inc.  
P.O. Box 988  
700 Orthopaedic Drive  
Warsaw, IN 46581-0988

**510(k) CONTACT:** Natalie S. Heck  
Manager, Regulatory Affairs

**TRADE NAME:** DePuy CMW 1 Bone Cement  
DePuy CMW 2 Bone Cement  
DePuy CMW 3 Bone Cement

**COMMON NAME:** Polymethyl Methacrylate (PMMA) Bone Cement

**CLASSIFICATION:** Class II; 21 CFR 888.3027

**DEVICE PRODUCT CODE:** LOD

**SUBSTANTIALLY EQUIVALENT DEVICES:** DePuy 1 Bone Cement (P960001/S003)\*  
DePuy 2 Bone Cement (P960001/S006)\*  
DePuy 3 Bone Cement (P960001/S004)\*  
SmartSet GMV Endurance Gentamicin Bone Cement (K033382).  
SmartSet MV Endurance Bone cement (P960001/S1)\* (previously branded Endurance Bone Cement)

\* DePuy 1 Bone Cement, DePuy 2 Bone Cement, DePuy 3 Bone Cement and SmartSet MV Endurance Bone Cement were approved by FDA under PMA Supplement, prior to the FDA reclassification of PMMA cement as Class II, effective August 16, 2002.

**DEVICE DESCRIPTION:**

DePuy CMW 1, 2 and 3 Bone Cements are self-curing cements. The cements allow the seating and securing of a metal or plastic prosthesis to living bone. The following modifications are being made:

Changes are being made to the formulation of the bone cement liquid components.

A warning is being deleted from the labeling for DePuy CMW 3 Bone Cement.

**INTENDED USE AND INDICATIONS:**

DePuy CMW 1, 2 and 3 Bone Cements are indicated for the fixation of prostheses to living bone in orthopaedic musculoskeletal surgical procedures for rheumatoid arthritis, osteoarthritis, traumatic arthritis, osteoporosis, avascular necrosis, collagen disease, severe joint destruction secondary to trauma or other conditions, and revision of previous arthroplasty.

**BASIS OF SUBSTANTIAL EQUIVALENCE:**

Based on similarities in formulations, manufacturing methods and intended use, DePuy believes that the modified DePuy CMW 1, 2 and 3 Bone Cements described in this submission are substantially equivalent to the previously cleared and approved bone cements.



NOV 22 2005

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Natalie Heck  
Manager, Regulatory Affairs  
DePuy Orthopaedics, Inc  
PO Box 988  
700 Orthopaedic Drive  
Warsaw, Indiana 46581-0988

Re: K053003

Trade/Device Name: DePuy CMW 1, 2 and 3 Bone Cements  
Regulation Number: 21 CFR 888.3027  
Regulation Name: Polymethylmethacrylate (PMMA) bone cement  
Regulatory Class: II  
Product Code: LOD  
Dated: October 24, 2005  
Received: October 27, 2005

Dear Ms. Heck:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



for

Mark N. Melkerson  
Acting Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications Statement

510(k) Number (if known):

Device Name: DePuy CMW 1, 2 and 3 Bone Cements

Indications for Use:

DePuy CMW 1, 2 and 3 Bone Cements are indicated for the fixation of prostheses to living bone in orthopaedic musculoskeletal surgical procedures for rheumatoid arthritis, osteoarthritis, traumatic arthritis, osteoporosis, avascular necrosis, collagen disease, severe joint destruction secondary to trauma or other conditions, and revision of previous arthroplasty.

Prescription Use ☒  
(Part 21 CFR 801.Subpart D)


OR/AND

Over-The Counter Use  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
**(Division Sign-Off)**  
**Division of General, Restorative,**  
**and Neurological Devices**

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**510(k) Number** K05300.3